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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,288	10/24/2001	W. Jerry Easterling	ERECTILE-NEW (US)	6875
7590 04/07/2004			EXAMINER	
DAVID G. HENRY 700 Texas Center P.O. Box 1470 Waco, TX 76703-1470			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/044,288	<b>Applicant(s)</b> EASTERLING, W. JERRY	
	<b>Examiner</b> San-ming Hui	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.  
     4a) Of the above claim(s) 1-15 and 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This application is a continuation-in-part of US Serial 09/411,175, which is a continuation-in-part of US Serial 09/128,103 filed August 3, 1998.

Applicant's response filed December 24, 2003 have been received.

Claims 1-15 and 18-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

This application contains claims 1-15 and 18-29 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 16-17 have been examined herein to the extent they read on the elected invention and species.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (Journal of Urology, 1994;151:1522-1524), reference of record in the IDS in view of Chien et al. (US Patent 4,690,683).

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Levine teaches localized delivery of verapamil to the lesion as useful in treating Peyronie's Disease, which is characterized by fibrous plaque involving the tunica albugines of the corpora cavernosa (see the abstract and page 1522, first paragraph).

Levine does not expressly teach verapamil is delivered by transdermal route of administration.

Chien et al. teaches a method of transdermal delivery of verapamil (See the abstract and claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ verapamil transdermally to treat fibrous plaque in the penis.

One of ordinary skill in the art would have been motivated to employ verapamil transdermally to treat fibrous plaque in the penis. It is known to employ verapamil in a localized delivery to treat Peyronie's Disease. Employing the transdermal system of Chien to deliver verapamil locally to the fibrous plaque in the penis would be reasonably expected to be effective in treating Peyronie's Disease since the selection of one or another route of administration would be seen as a simple selection from among obvious alternatives.

### ***Response to Arguments***

Applicant argues that the herein claimed invention not being obvious over the cited prior art because one of ordinary skill in the art would be using alternative routes of administration instead of injection, especially transdermal route of administering verapamil was known at that time. Such arguments have been carefully considered, but

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are not found persuasive. The fact that the cited prior art do not expressly use transdermal administration of verapamil to treat Peyronie's disease does not render the herein claimed invention unobvious. The cited prior art clearly provides motivation to combine the teachings to arrive at the herein claimed invention. Locally administration of verapamil is known to be useful in treating Peyronie's disease. Absent evidence to the contrary, employing the transdermal system of Chien to deliver verapamil locally to the fibrous plaque in the penis would be reasonably expected to be effective in treating Peyronie's Disease since the selection of one or another route of administration would be seen as a simple selection from among obvious alternatives.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-

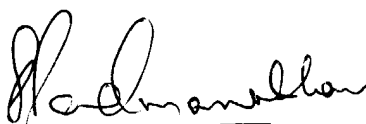
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1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui  
Patent Examiner  
Art Unit 1617

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**

4/2/04